



PATENT
Customer No. 22,852
Attorney Docket No. 06028.0037-00

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of:

Isabelle PREUILH et al.

Application No.: 09/709,477

Filed: November 13, 2000

For: FOAMING COMPOSITION FOR TREATING
THE HAIR

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) Group Art Unit: 1617
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) Examiner: A.M. COTTON
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) Confirmation No. 4547
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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

DECLARATION UNDER 37 C.F.R. § 1.132

I, Isabelle PREUILH, declares and states that,

- I am a French citizen residing at 12 rue des Moulières –Elegancia C – 06110 le Cannet, FRANCE ;
- I am a Doctor in Pharmacy graduated from the University of Pharmacy in Bordeaux
- I am employed by GALDERMA as a pharmaceutical project manager and have experience working with hair care compositions ;
- At the time of the invention I was Head of Formulation group at Galderma R&D
- I am a named inventor and am familiar with the United States patent application No. 10/709,477 filed on November 13, 2000. for FOAMING COMPOSITION FOR TREATING THE HAIR ;
- I have read and am familiar with the prior art references cited by the Examiner, and more particularly US 4,722,837 (Cameron et al),
- given my education and experience, particularly in the area of hair care, I consider myself able to provide the following testimony based on experiments conducted or under my supervision:

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COMPARATIVE TESTS

The shampoo sold under the trade name Clobex®, which composition corresponds to that of Example VIII of the invention, a composition according to Example VIII of the invention without the active principle, namely clobetasol propionate (composition A), a composition containing no ethanol (composition B), a composition according to Cameron et al (composition C) and a composition according to Cameron et al wherein an ethanol content of 10 % by weight was introduced (composition D) were prepared. The viscosity and the foaming power were then measured and compared.

I. COMPOSITIONS TESTED

The following compositions were prepared from the following ingredients and the quantities were expressed in % by weight relative to the total weight of the composition.

Ingredients	Clobex® shampoo (example VII) of the invention)	Composition A	Composition B
Citric acid monohydrate	0.24	0.24	0.24
Sodium citrate dehydrate ⁽¹⁾	2.6	2.6	2.6
Polyquaternium 10 ⁽²⁾	2.0	2.0	2.0
Sodium lauryl ether sulfate ⁽³⁾	17.0	17.0	17.0
Cocoyl betaine ⁽⁴⁾	6.0	6.0	6.0
Clobetasol propionate	0.05	-	-
Ethanol	10.0	10.0	0.0
Water qsp	100	100	100

⁽¹⁾ sold under the trade name Sodium citrate USP 2H2O by the society COOPER.

⁽²⁾ sold under the trade name Celquat SC240C by the society National Starch & Chemical

⁽³⁾ sold under the trade name Texapon N70 by the society Cognis

⁽⁴⁾ sold under the trade name Dchyton AB 30 by the society Cognis

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Ingredients	Composition C (Example I of Cameron et al)	Composition D
Sodium lauryl ether sulfate ⁽¹⁾	17.0	17.0
Cocoyl betaine ⁽²⁾	6.0	6.0
TEA dodecylbenzenesulfonate ⁽³⁾	0.5	0.5
Cocamide DEA ⁽⁴⁾	2.0	2.0
Sodium chloride	1.0	1.0
Menthol	0.5	0.5
PEG-120methyl glucosc dioleate	0.5	0.5
Methylparaben	0.1	0.1
Phosphoric acid	0.1	0.1
Ethanol	0.0	10.0
Water qsp	100	100

⁽¹⁾ sold under the trade name Texapon N70 by the society Cognis

⁽²⁾ sold under the trade name Dchyton AB 30 by the society Cognis

⁽³⁾ sold under the trade name Marlopon AT50 by the society Sasol.

⁽⁴⁾ sold under the trade name Rewomid DC 212S by the society Degussa.

II. STUDY OF THE VISCOSITY

II.1 Measurement

The measurement of the viscosity was carried out with a Rheomat RM180. Different rotors (M_4 , M_3 , M_2) (cf table 1) were used depending on the product's viscosity. The higher the viscosity is, the bigger number of rotor has to be used. For example, if a product has a high viscosity, the M_4 rotor is chosen.

Table 1

Rotor	Range of viscosity (in Poise (P) or centipoises (cP))
M_4	12 P-236 P
M_3	1.8 P-40.2 P
M_2	20 cP-732 cP

The viscosity was measured with about 20 g of each composition under the conditions indicated in the table 2 below:

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Table 2

Parameter	Value
Shearing rate (s^{-1})	200
Temperature ($^{\circ}C$)	22
Number of measure for 1 product	1
Duration of a measure (min)	10

II.2 Results

The following results were obtained and indicated in table 3 below.

Table 3

Formula	Viscosity (Poise)
Clobex® shampoo	M_3 ; 7.8
Composition A	M_3 ; 7.3
Composition B	M_4 ; 25.5
Composition C	M_4 ; 68.2
Composition D	No value of viscosity can be obtained with any of the rotor M_4 , M_3 , M_2 because it is too low.

II.3 Conclusion

The difference between Clobex® shampoo and composition A is the active principle. According to the results, there is no difference between the two viscosity values obtained with the two compositions. Consequently, the active principle has no influence on the viscosity.

The use of 10 % by weight of ethanol leads to a decrease of the viscosity when composition A is compared to composition B wherein no ethanol is used. However, the addition of ethanol leads to a composition whose viscosity can still be measured contrary to compositions of the prior art (see compositions C and D). Therefore, the use of ethanol in compositions of the invention leads to compositions which are not too liquid and which can be spread easily.

The composition C according to Cameron et al is really more viscous than composition A according to the invention. This composition C is too viscous to be spread easily as a medicated shampoo.

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After addition of ethanol to the composition C, leading to composition D, the viscosity can not be measured. The composition became too liquid and viscosity is totally broken with ethanol.

Therefore, the use of ethanol as propenetrating agent in compositions according to the invention has surprisingly and unexpectedly only few impact on the viscosity.

III. STUDY OF THE FOAMING POWER

III.1 Measurement

The study of the foaming power was carried out with the Sira Foam Tester R2000 of Sodexim SAS. This device may be used to measure the volume of foam generated by agitation.

The principle of measurement consists in that the shampoo arrives by a flexible pipe in the tank having double wall traversed by thermo-controlled water. Foam is generated by a rotor.

The measure of the foam volume is carried out with different needles.

A cycle of measurement is divided into 2 stages:

- 1st stage: the rotor turns with a definite speed and during a fixed time.
- 2nd stage: when the rotor is stopped, the needles get off and touch the foam. The foam volume is thus measured.

The foaming power is obtained by the measure of the foam height each 10 s. during 2 min.

The operating conditions are indicated in the table 4 below.

Table 4

Parameters	Value
Temperature of water	30°C +/-2°C
Stirring velocity	1100 rpm
Time of stirring	10 s.
Concentration of the tested solution, which volume is 1000 ml	1%
Number of measurement which are performed during a cycle	3
Volume of shampoo necessary for a measurement	270 ml
Number of measurement of foam volume which are performed during a measurement	12

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III.2 Results

The following results were obtained and indicated in table 5 below.

Table 5

Formula	Mean foam power value (ml)	Variation coefficient
CLOBEX® Shampoo	769	0.4
Composition A	770.5	0.3
Composition B	769	0.5
Composition C	793.3	0.9
Composition D	772.3	0.7

III.3 Conclusion

The low variation coefficients mean that stable foaming power is obtained for each composition.

The active principle has no impact on the foaming power when Clobex® Shampoo is compared to composition A.

There is also no difference between the foam powers of compositions A and B. Alcohol has no adverse effect on the foam power of the compositions of the invention.

On the other hand, the addition of ethanol in composition D according to Cameron et al results in a significant decrease of the foam power of about 20 ml.

The results of these tests surprisingly and unexpectedly show that the viscosity is not much affected by ethanol in the compositions of the invention, and that the foaming power remains the same contrary to compositions according to Cameron wherein ethanol is added.

I further declare that all statements made herein of my own knowledge are true and that all statements are made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Dated: 15 February 2007

By: 

Isabelle PREUILH